IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLORADO

CLARK HOLLIS, surviving spouse, and LISA WEEMS, surviving daughter of CAROL HOLLIS, deceased,

Plaintiffs,

vs. **Civil Action No. 07-CV-00783-RPM-MEH**

PFIZER INC., a Delaware Corporation,

Defendant.

DEFENDANT PFIZER INC.'S ANSWER TO PLAINTIFFS' COMPLAINT

NOW COMES Defendant Pfizer Inc. (hereinafter "Pfizer"), and files this its Answer to Plaintiffs' Complaint ("Complaint"), and would respectfully show the Court as follows:

I.
ORIGINAL ANSWER

Response to Allegations Regarding Jurisdiction and Venue

1. Defendant is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 1 of the Complaint, and therefore denies the same.

2. Defendant admits that Pfizer is a Delaware corporation with its principal place of business in New York. Defendant denies the remaining allegations in Paragraph 2 of the Complaint.

3. Defendant is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 3 of the Complaint regarding whether Decedent took Celebrex® and therefore denies the same. Defendant denies any wrongful conduct, denies that

Celebrex® caused Plaintiffs or Decedent injury or damages, and denies the remaining allegations contained in Paragraph 3 of the Complaint.

4. Defendant is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 4 of the Complaint regarding the amount in controversy and therefore denies the same. Defendant admits that Plaintiffs claim that the amount in controversy exceeds $75,000.

5. Defendant is without knowledge or information sufficient to form a belief as to the truth of the allegations regarding Plaintiffs' citizenship and the amount in controversy, and therefore denies the same. However, Defendant admits that Plaintiffs claim the parties are diverse and that the amount in controversy exceeds $75,000. Defendant denies the remaining allegations in Paragraph 5 of the Complaint.

Response to General Allegations

6. Defendant is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 6 of the Complaint regarding whether Decedent took Celebrex®, whether Decedent exhibited symptoms of arthritis, and the conduct of Decedent's physician, and therefore denies the same. Defendant admits that, during certain periods of time, it marketed and co-promoted Celebrex® throughout the United States to be prescribed by healthcare providers who are authorized by law to prescribe drugs in accordance with their approval by the FDA. Defendant denies the remaining allegations in Paragraph 6 of the Complaint.

7. Defendant is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 7 of the Complaint and therefore denies the same.

8. Defendant is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 8 of the Complaint regarding whether Decedent took

Celebrex® whether Decedent's death was the result of a cardiac event, and the date of Decedent's death, and therefore denies the same. Defendant denies causing Plaintiffs or Decedent an injury or damages and denies the remaining allegations in Paragraph 8 of the Complaint.

Response to First Cause of Action: Strict Liability

9. Defendant incorporates by reference its responses to each paragraph of Plaintiffs' Complaint as if fully set forth herein.

10. Defendant admits that, during certain periods of time, it marketed and co-promoted Celebrex® throughout the United States to be prescribed by healthcare providers who are authorized by law to prescribe drugs in accordance with their approval by the FDA. Defendant states that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant denies any wrongful conduct and denies the remaining allegations in Paragraph 10 of the Complaint.

11. Defendant states that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant denies the allegations in Paragraph 11 of the Complaint.

12. Defendant states that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant denies any wrongful conduct and denies the remaining allegations in Paragraph 12 of the Complaint.

13. Defendant states that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant denies any wrongful conduct, denies that Celebrex® caused Plaintiffs or Decedent any injury or damages, and denies the remaining allegations in Paragraph 13 of the Complaint.

14. Defendant denies any wrongful conduct, denies that Celebrex® caused Plaintiffs or Decedent any injury or damages, and denies the remaining allegations in Paragraph 14 of the Complaint.

Response to Second Cause of Action: Negligent Failure to Warn

15. Defendant incorporates by reference its responses to each paragraph of Plaintiffs' Complaint as if fully set forth herein.

16. Paragraph 16 of the Complaint contains legal contentions to which no response is required. To the extent that a response is deemed required, Defendant states that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant admits that it has duties as are imposed by law, but denies that it breached any such duties. Defendant denies the remaining allegations in Paragraph 16 of the Complaint.

17. Defendant states that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing

information, which was at all times adequate and comported with applicable standards of care and law. Defendant denies any wrongful conduct, denies that Celebrex® caused Plaintiffs or Decedent any injury or damages, and denies the remaining allegations in Paragraph 17 of the Complaint.

18. Defendant states that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant denies any wrongful conduct, denies that Celebrex® caused Plaintiffs or Decedent any injury or damages, and denies the remaining allegations in Paragraph 18 of the Complaint.

Defendant denies the allegations contained in the unnumbered paragraph following Paragraph 18 of the Complaint.

III.
GENERAL DENIAL

Defendant denies all allegations and/or legal conclusions set forth in Plaintiffs' Complaint that have not been previously admitted, denied, or explained.

IV.
AFFIRMATIVE DEFENSES

Defendant reserves the right to rely upon any of the following or additional defenses to claims asserted by Plaintiffs to the extent that such defenses are supported by information developed through discovery or evidence at trial. Defendant affirmatively shows that:

First Defense

1. The Complaint fails to state a claim upon which relief can be granted.

Second Defense

2. Celebrex® is a prescription medical product. The federal government has preempted the field of law applicable to the labeling and warning of prescription medical

products. Defendant's labeling and warning of Celebrex® was at all times in compliance with applicable federal law. Plaintiffs' causes of action against Defendant, therefore, fail to state a claim upon which relief can be granted; such claims, if allowed, would conflict with applicable federal law and violate the Supremacy Clause of the United States Constitution.

Third Defense

3. At all relevant times, Defendant provided proper warnings, information and instructions for the drug in accordance with generally recognized and prevailing standards in existence at the time.

Fourth Defense

4. At all relevant times, Defendant's warnings and instructions with respect to the use of Celebrex® conformed to the generally recognized, reasonably available, and reliable state of knowledge at the time the drug was manufactured, marketed and distributed.

Fifth Defense

5. Plaintiffs' claims are barred and/or limited in accordance with Colo. Rev. Stat. §§ 13-21-401 through 13-21-406 and Colo. Rev. Stat. §§ 13-21-102, 102.5, 111.5, 111.6 and 111.7.

Sixth Defense

6. Plaintiffs' action is time-barred as it is filed outside of the time permitted by the applicable Statute of Limitations, and same is plead in full bar of any liability as to Defendant.

Seventh Defense

7. Plaintiffs' action is barred by the statute of response.

Eighth Defense

8. Plaintiffs' claims against Defendant are barred to the extent Plaintiffs and/or Decedent were contributorily negligent, actively negligent or otherwise failed to mitigate their damages, and any recovery by Plaintiffs should be diminished accordingly.

Ninth Defense

9. The proximate cause of the loss complained of by Plaintiffs is not due to any acts or omissions on the part of Defendant. Rather, said loss is due to the acts or omissions on the part of third parties unrelated to Defendant and for whose acts or omissions Defendant is not liable in any way.

Tenth Defense

10. The acts and/or omissions of unrelated third parties as alleged constituted independent, intervening causes for which Defendant cannot be liable.

Eleventh Defense

11. Any injuries or expenses incurred by Plaintiffs and/or Decedent were not caused by Celebrex®, but were proximately caused, in whole or in part, by an idiosyncratic reaction, operation of nature, or act of God.

Twelfth Defense

12. Defendant affirmatively denies that they violated any duty owed to the Plaintiffs and/or Decedent.

Thirteenth Defense

13. A manufacturer has no duty to warn patients or the general public of any risk, contraindication, or adverse effect associated with the use of a prescription medical product. Rather, the law requires that all such warnings and appropriate information be given to the prescribing physician and the medical profession, which act as a "learned intermediary" in determining the use of the product. Celebrex® is a prescription medical product, available only on the order of a licensed physician. Celebrex® provided an adequate warning to Plaintiffs' treating and prescribing physicians.

Fourteenth Defense

14. The product at issue was not in a defective condition or unreasonably dangerous at the time it left the control of the manufacturer or seller.

Fifteenth Defense

15. Celebrex® was at all times material to the Complaint reasonably safe and reasonably fit for its intended use and the warnings and instructions accompanying Celebrex® at the time of the occurrence of the injuries alleged by Plaintiffs were legally adequate for its approved usages.

Sixteenth Defense

16. Plaintiffs' causes of action are barred in whole or in part by the lack of a defect as the Celebrex® allegedly ingested by Decedent were prepared in accordance with the applicable standard of care.

Seventeenth Defense

17. Plaintiffs' and/or Decedent's alleged injuries/damages, if any, were the result of misuse or abnormal use of the product Celebrex® after the product left the control of Defendant and any liability of Defendant is therefore barred.

Eighteenth Defense

18. Plaintiffs' and/or Decedent's alleged damages were not caused by any failure to warn on the part of Defendant.

Nineteenth Defense

19. Plaintiffs' and/or Decedents' alleged injuries/damages, if any, were the result of preexisting or subsequent conditions unrelated to Celebrex®.

Twentieth Defense

20. Decedent knew or should have known of any risk associated with Celebrex®; therefore, the doctrine of assumption of the risk bars or diminishes any recovery.

Twenty-first Defense

21. Plaintiffs are barred from recovering against Defendant because Plaintiffs' claims are preempted in accordance with the Supremacy Clause of the United States Constitution and by the Federal Food, Drug and Cosmetics Act, 21 U.S.C. § 301 et. seq.

Twenty-second Defense

22. Plaintiffs' claims are barred in whole or in part under the applicable state law because the subject pharmaceutical product at issue was subject to and received pre-market approval by the Food and Drug Administration under 52 Stat. 1040, 21 U.S.C. § 301.

Twenty-third Defense

23. The manufacture, distribution and sale of the pharmaceutical product referred to in Plaintiffs' Complaint were at all times in compliance with all federal regulations and statutes, and Plaintiffs' causes of action are preempted.

Twenty-fourth Defense

24. Plaintiffs' claims are barred in whole or in part by the deference given to the primary jurisdiction of the Food and Drug Administration over the subject pharmaceutical product at issue under applicable federal laws, regulations, and rules.

Twenty-fifth Defense

25. Plaintiffs' claims are barred in whole or in part because there is no private right of action concerning matters regulated by the Food and Drug Administration under applicable federal laws, regulations, and rules.

Twenty-sixth Defense

26. Plaintiffs' claims are barred in whole or in part because Defendant provided adequate "direction or warnings" as to the use of the subject pharmaceutical product within the meaning of Comment j to Section 402A of the Restatement (Second) of Torts.

Twenty-seventh Defense

27. Plaintiffs' claims are barred or limited to a product liability failure to warn claim because Celebrex® is a prescription pharmaceutical drug and falls within the ambit of Restatement (Second) of Torts § 402A, Comment k.

Twenty-eighth Defense

28. Plaintiffs' claims are barred in whole or in part because the subject pharmaceutical product at issue "provides net benefits for a class of patients" within the meaning of Comment f to § 6 of the Restatement (Third) of Torts: Products Liability.

Twenty-ninth Defense

29. Plaintiffs' claims are barred under § 4, et seq., of the Restatement (Third) of Torts: Products Liability.

Thirtieth Defense

30. To the extent that Plaintiffs are seeking punitive damages, Plaintiffs have failed to plead facts sufficient under the law to justify an award of punitive damages.

Thirty-first Defense

31. The imposition of punitive damages in this case would violate Defendant's rights to procedural due process under both the Fourteenth Amendment of the United States Constitution and Article I, § 17 of the Constitution of the State of Colorado, and would additionally violate Defendant's right to substantive due process under the Fourteenth Amendment of the United States Constitution.

Thirty-second Defense

32. Plaintiffs' claims for punitive damages are barred, in whole or in part, by the Fifth and Fourteenth Amendments to the United States Constitution and are subject to all provisions of Colorado law.

Thirty-third Defense

33. The imposition of punitive damages in this case would violate the First Amendment to the United States Constitution.

Thirty-fourth Defense

34. Plaintiffs' punitive damage claims are preempted by federal law.

Thirty-fifth Defense

35. In the event that reliance was placed upon Defendant's nonconformance to an express representation, this action is barred as there was no reliance upon representations, if any, of Defendant.

Thirty-sixth Defense

36. Plaintiffs failed to provide Defendant with timely notice of any alleged nonconformance to any express representation.

Thirty-seventh Defense

37. To the extent that Plaintiffs' claims are based on a theory providing for liability without proof of causation, the claims violate Defendant's rights under the United States Constitution.

Thirty-eighth Defense

38. Plaintiffs' claims are barred, in whole or in part, because the advertisements, if any, and labeling with respect to the subject pharmaceutical products were not false or misleading and, therefore, constitute protected commercial speech under the applicable provisions of the United States Constitution.

Thirty-ninth Defense

39. To the extent that Plaintiffs seek punitive damages for the conduct which allegedly caused injuries asserted in the Complaint, punitive damages are barred or reduced by applicable law or statute or, in the alternative, are unconstitutional insofar as they violate the due process protections afforded by the United States Constitution, the excessive fines clause of the Eighth Amendment of the United States Constitution, the Commerce Clause of the United States Constitution, the Full Faith and Credit Clause of the United States Constitution, and applicable provisions of the Constitution of the State of Colorado. Any law, statute, or other authority purporting to permit the recovery of punitive damages in this case is unconstitutional, facially and as applied, to the extent that, without limitation, it: (1) lacks constitutionally sufficient standards to guide and restrain the jury's discretion in determining whether to award punitive damages and/or the amount, if any; (2) is void for vagueness in that it failed to provide adequate advance notice as to what conduct will result in punitive damages; (3) permits recovery of punitive-damages based on out-of state conduct, conduct that complied with applicable law, or conduct that was not directed, or did not proximately cause harm, to Plaintiffs; (4) permits recovery of punitive damages in an amount that is not both reasonable and proportionate to the amount of harm, if any, to Plaintiffs and to the amount of compensatory damages, if any; (5) permits jury consideration of net worth or other financial information relating to Defendant; (6) lacks constitutionally sufficient standards to be applied by the trial court in post-verdict review of any punitive damages awards; (7) lacks constitutionally sufficient standards for appellate review of punitive damages awards; and (8) otherwise fails to satisfy Supreme Court precedent, including, without limitation, Pacific Mutual Life Ins. Co. v. Haslip, 499 U.S. 1, 111 (1991), TXO Production Corp. v. Alliance Resources, Inc., 509 U.S. 443 (1993); BMW of North

America, Inc. v. Gore, 519 U.S. 559 (1996); and State Farm Mut. Auto Ins. Co. v. Campbell, 538 U.S 408.

Fortieth Defense

40. The methods, standards, and techniques utilized with respect to the manufacture, design, and marketing of Celebrex®, if any, used in this case, included adequate warnings and instructions with respect to the product's use in the package insert and other literature, and conformed to the generally recognized, reasonably available, and reliable state of the knowledge at the time the product was marketed.

Forty-first Defense

41. The claims asserted in the Complaint are barred because Celebrex® was designed, tested, manufactured and labeled in accordance with the state-of-the art industry standards existing at the time of the sale. Col. Rev. Stat. Ann. § 13-21-403(1)(b).

Forty-second Defense

42. If Plaintiffs and/or Decedent sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries and losses were caused by the actions of persons not having real or apparent authority to take said actions on behalf of Defendant and over whom Defendant had no control and for whom Defendant may not be held accountable.

Forty-third Defense

43. The claims asserted in the Complaint are barred, in whole or in part, because Celebrex® was not unreasonably dangerous or defective, was suitable for the purpose for which it was intended, and was distributed with adequate and sufficient warnings.

Forty-fourth Defense

44. Plaintiffs' claims are barred, in whole or in part, by the equitable doctrines of laches, waiver, and/or estoppel.

Forty-fifth Defense

45. Plaintiffs' claims are barred because Decedents' injuries, if any, were the result of the pre-existing and/or unrelated medical, genetic and/or environmental conditions, diseases or illnesses, subsequent medical conditions or natural courses of conditions of Decedent, and were independent of or far removed from Defendant's conduct.

Forty-sixth Defense

46. The claims asserted in the Complaint are barred, in whole or in part, because Celebrex® did not proximately cause injuries or damages to Plaintiffs or Decedent.

Forty-seventh Defense

47. The claims asserted in the Complaint are barred, in whole or in part, because Plaintiffs and Decedent did not incur any ascertainable loss as a result of Defendant's conduct.

Forty-eighth Defense

48. The claims asserted in the Complaint are barred, in whole or in part, because the manufacturing, labeling, packaging, and any advertising of the product complied with the applicable codes, standards and regulations established, adopted, promulgated or approved by any applicable regulatory body, including but not limited to the United States, any state, and any agency thereof.

Forty-ninth Defense

49. The claims must be dismissed because Decedent would have taken Celebrex® even if the product labeling contained the information that Plaintiffs contend should have been provided.

Fiftieth Defense

50. The claims asserted in the Complaint are barred because the utility of Celebrex® outweighed its risks.

Fifty-first Defense

51. Plaintiffs' and Decedent's damages, if any, are barred or limited by the payments received from collateral sources.

Fifty-second Defense

52. Defendant's liability, if any, can only be determined after the percentages of responsibility of all persons who caused or contributed toward Plaintiffs' alleged damages, if any, are determined. Defendant seeks an adjudication of the percentage of fault of the claimants and each and every other person whose fault could have contributed to the alleged injuries and damages, if any, of Plaintiffs.

Fifty-third Defense

53. Plaintiffs' claims are barred, in whole or in part, by the doctrine of abstention in that the common law gives deference to discretionary actions by the United States Food and Drug Administration under the Federal Food, Drug, and Cosmetic Act.

Fifty-forth Defense

54. The claims asserted in the Complaint are barred, in whole or in part, because Celebrex® is comprehensively regulated by the FDA pursuant to the Federal Food, Drug & Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301 *et seq*., and regulations promulgated there under, and Plaintiffs' claims conflict with the FDCA, with the regulations promulgated by FDA to implement the FDCA, with the purposes and objectives of the FDCA and FDA's implementing regulations, and with the specific determinations by FDA specifying the language that should be used in the labeling accompanying Celebrex®. Accordingly, Plaintiffs' claims are preempted by the Supremacy Clause of the United States Constitution, Article VI, clause 2, and the laws of the United States.

Fifty-fifth Defense

55. Defendant reserves the right to supplement its assertion of defenses as it continues with its factual investigation of Plaintiffs' claims.

Fifty-sixth Defense

56. Defendant made no warranties of any kind, express or implied, or any representations of any nature whatsoever to Plaintiffs or Decedent herein. Additionally, as a manufacturer and not a seller, Defendant is not subject to liability for implied warranties without privy, i.e., proof of direct and specific transactions between Decedent and Defendant. If any such warranties were made, whether express or implied, which Defendant specifically denies, then Plaintiffs or Decedent failed to give timely notice of such breach therefore as required under Colo. Rev. Stat. Ann. § 4-2-607(3)(a).

V.
JURY DEMAND

Defendant hereby demands a trial by jury.

VI.
PRAYER

WHEREFORE, Defendant Pfizer Inc. prays that Plaintiffs take nothing by their suit, that Pfizer be discharged with its costs expended in this matter, and for such other and further relief to which Pfizer may justly be entitled.

Respectfully submitted this 15TH day of May, 2007.

s/K. Michelle Anderson
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CERTIFICATE OF SERVICE

I hereby certify that on this 15th day of May, 2007, I electronically filed the foregoing with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the following e-mail addresses, and I hereby certify that I have mailed or served the foregoing to the following non CM/ECF participants in the matter indicated by the non-participant's name:

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